

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application	) <u>PATENT APPLICATION</u>
	)
Inventor(s): Michael G. Kahn, M.D., Ph.D;	) Art Unit:
Michael Mischke-Reeds	)
	) Examiner:
SC/Serial No.: Unknown	)
	)
Filed: Herewith	)
	)
Title: CLINICAL TRIALS MANAGEMENT SYSTEM	)
AND METHOD	)
_____	)

DECLARATION FOR PATENT APPLICATION

As a below named inventor, I hereby declare that my residence, post office address and citizenship are as stated below next to my name; I believe that I am the original, first and sole inventor (if one name is listed below), first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

CLINICAL TRIALS MANAGEMENT SYSTEM AND METHOD

the specification of which (check applicable ones):

☒ is filed herewith;

☐ was filed with the above-identified "Filed" date and "SC/Serial No."

☐ was amended on (or amended through) \_\_\_\_.

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment(s) referred to above. I acknowledge the duty to disclose information which is material to the examination of the application in accordance with Title 37, Code of Federal Regulations, § 1.56.

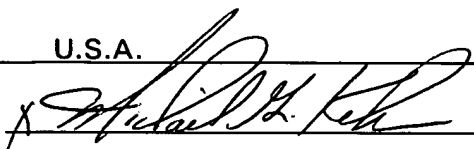
I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under § 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

(1) Full name of sole  
or first inventor: Michael G. Kahn, M.D., Ph.D

(1) Residence: 3980 Greenbriar Blvd.  
Boulder, CO 80303

(1) Post Office Address: (Same)

(1) Citizenship: U.S.A.

(1) Inventor's signature: X 

(1) Date: X 13 May 00

\*\*\*\*\*

(2) Full name of second  
joint inventor: Michael Mischke-Reeds

(2) Residence: 44 Brentwood Avenue  
San Francisco, CA 94127

(2) Post Office Address: (Same)

(2) Citizenship: U.S.A.

(2) Inventor's signature: X

(2) Date: X

(1) Date: X 13 MAY 00

\*\*\*\*\*

(2) Date: X 5/30/00

\*\*\*\*\*

Title 37, Code of Federal Regulations, §1.56

**SECTION 1.56. DUTY TO DISCLOSE INFORMATION  
MATERIAL TO PATENTABILITY**

(a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclose information exists with respect to each pending claim until the claim is cancelled or withdrawn from consideration, or the application becomes abandoned. Information material to the patentability of a claim that is cancelled or withdrawn from consideration need not be submitted if the information is not material to the patentability of any claim remaining under consideration in the application. There is no duty to submit information which is not material to the patentability of any existing claim. The duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by §§1.97(b)-(d) and 1.98.\* However, no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct. The Office encourages applicants to carefully examine:

- (1) prior art cited in search reports of a foreign patent office in a counterpart application, and
- (2) the closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines, to make sure that any material information contained therein is disclosed to the Office.

(b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and

(1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or

(2) It refutes, or is inconsistent with, a position the applicant takes in:

- (i) Opposing an argument of unpatentability relied on by the Office; or
- (ii) Asserting an argument of patentability.

A prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

(c) Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

- (1) Each inventor named in the application;
- (2) Each attorney or agent who prepares or prosecutes the application; and
- (3) Every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application.

(d) Individuals other than the attorney, agent or inventor may comply with this section by disclosing information to the attorney, agent, or inventor.

\* §§1.97(b)-(d) and 1.98 relate to the timing and manner in which information is to be submitted to the Office.

\*\*\*\*\*

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application ) PATENT APPLICATION  
Inventor(s): Michael G. Kahn, M.D., Ph.D; )  
Michael Mischke-Reeds ) Art Unit:  
SC/Serial No.: Unknown )  
Filed: Herewith ) Examiner:  
Title: CLINICAL TRIALS MANAGEMENT SYSTEM )  
AND METHOD )

POWER OF ATTORNEY BY ASSIGNEE UNDER 37 C.F.R. §§3.71, 3.73(b)

Assistant Commissioner for Patents  
Washington, DC 20231

Sir:

The below-identified Assignee is the owner of the entire right, title and interest in the above-identified patent application by virtue of an assignment from the inventor(s).

\_\_\_ The assignment was recorded in the United States Patent and Trademark Office at Reel \_\_\_, Frames \_\_\_ - \_\_\_, or

☒ A true copy of the assignment is attached hereto, the original of which has been (or is herewith) forwarded to the United States Patent and Trademark Office for recording.

The undersigned (whose title is supplied below) is empowered to sign this statement on behalf of the Assignee.

Assignee hereby appoints WARREN S. WOLFELD, Reg. No. 31,454, D. BENJAMIN BORSON, Reg. No. 42,349, and other attorneys of FLIESLER, DUBB, MEYER & LOVEJOY LLP, to prosecute this application and transact all business in the United States Patent & Trademark Office connected therewith; said appointment to be to the exclusion of the inventor(s) and the inventor's(s') attorney(s) in accordance with the provisions of 37 C.F.R. §3.71.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Please address all correspondence to:

Warren S. Wolfeld  
FLIESLER, DUBB, MEYER & LOVEJOY LLP (415) 362-3800  
Four Embarcadero Center, Suite 400  
San Francisco, CA 94111-4156

Please direct all telephone calls to:

Warren S. Wolfeld

Assignee: FastTrack Systems, Inc.

Assignee Type: (Corporation, Partnership, ...) Corporation

Signor's Name: Michael G. Kahn, M.D., Ph.D.

Signor's Title: (Corporate Office or Position) Vice President

Signature: 

Date: X 13 May 00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application

) PATENT APPLICATION

Inventor(s): Michael G. Kahn, M.D., Ph.D;  
Michael Mischke-Reeds

) Art Unit:

) Examiner:

SC/Serial No.: Unknown

Filed: Herewith

Title: CLINICAL TRIALS MANAGEMENT SYSTEM  
AND METHOD

**STATEMENT CLAIMING SMALL ENTITY STATUS**  
**37 C.F.R §1.9(f) AND §1.27(c) - SMALL BUSINESS CONCERN**

I hereby declare that I am:

\_\_\_ The owner of the small business concern identified below.

☒ An official of the small business concern empowered to act on behalf of the concern identified below.

Name: FastTrack Systems, Inc.

Address: 2955 Campus Drive, Suite 350, San Mateo, CA 94403

I hereby declare that the above identified small business concern qualifies as a small business concern as defined in 13 C.F.R. §121.12, and reproduced in 37 C.F.R. §1.9(d), for purposes of paying reduced fees under Section 41(a) and (b) of Title 35 U.S.C. in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third-party or parties controls or has the power to control both.

I hereby declare that rights under contract or law have been conveyed to and remain with the small business concern identified below with regard to the invention identified by the above TITLE and INVENTOR(S), and described in:

☒ the Specification filed herewith

\_\_\_ the Application having the above SC/Serial No. and Filed date

\_\_\_ Patent No. \_\_\_\_\_ issued \_\_\_\_\_

If the rights held by the above-identified small business concern are not exclusive, each individual, concern or organization having rights to the invention is listed below\* and no rights to the invention are held by any person, other than the inventor, who could not qualify as an independent inventor under 37 C.F.R. §1.9(c) or by any concern which would not qualify as a small business concern under 37 C.F.R. §1.9(d) or a nonprofit organization under 37 C.F.R. §1.9(e).

NAME: \_\_\_\_\_

ADDRESS: \_\_\_\_\_

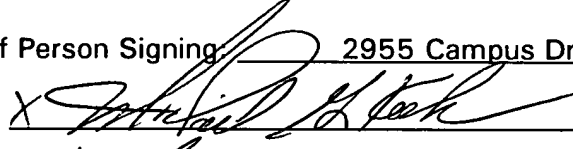
☐ Individual ☐ Small Business Concern ☐ Nonprofit Organization

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small business entity is no longer appropriate. (37 C.F.R. §1.28(b)).

Name of Person Signing: Michael G. Kahn, M.D., Ph.D.

Title of Person Signing: Vice President

Address of Person Signing: 2955 Campus Drive, Suite 350, San Mateo, CA 94403

Signature: X 

Date: X 13 May 00

\*\*\*\*\*

\* Note: Separate statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 C.F.R. §1.27).

\*\*\*\*\*

**Title 37, Code of Federal Regulations, §1.9(c-f)**

(c) An **independent inventor** as used in this chapter means any inventor who (1) has not assigned, granted, conveyed, or licensed, and (2) is under no obligation under contract or law to assign, grant, convey, or license, any rights in the invention to any person who could not likewise be classified as an independent inventor if that person had made the invention, or to any concern which would not qualify as a small business concern or a nonprofit organization under this section.

(d) A **small business concern** as used in this chapter means any business concern meeting the size standards set forth in 13 C.F.R. Part 121 to be eligible for reduced patent fees. Questions related to size standards for a small business concern may be directed to: Small Business Administration, Size Standards Staff, 409 Third Street, SW, Washington, DC 2041.

(e) A **nonprofit organization** as used in this chapter means (1) a university or other institution of higher education located in any country; (2) an organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1954 (26 U.S.C. 501(c)(3)) and exempt from taxation under section 501(a) of the Internal Revenue Code (26 U.S.C. 501(a)); (3) any nonprofit scientific or educational organization qualified under a nonprofit organization statute of a state of this country (35 U.S.C. 201(i)); or (4) any nonprofit organization located in a foreign country which would qualify as a nonprofit organization under paragraphs (e) (2) or (3) of this section if it were located in this country.

(f) A **small entity** as used in this chapter means an **independent inventor**, a **small business concern** or a **nonprofit organization** eligible for reduced patent fees.

\*\*\*\*\*

**Title 13, Code of Federal Regulations, §121.12**

**121.12 Small business for paying reduced patent fees.** (a) Pursuant to Pub. L. 97-247, a small business concern for purposes of paying reduced fees under 35 U.S. Code 41 (a) and (b) to the Patent and Trademark Office means any business concern (1) whose number of employees, including those of its affiliates, does not exceed 500 persons and (2) which has not assigned, granted, conveyed, or licensed, and is under no obligation under contract or law to assign, grant, convey or license, any rights in the invention to any person who could not be classified as an independent inventor if that person had made the invention, or to any concern which would not qualify as a small business concern or a nonprofit organization under this section. For the purpose of this section concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both. The number of employees of the business concern is the average over the fiscal year of the persons employed during each of the pay periods of the fiscal year. Employees are those persons employed on a full-time, part-time or temporary basis during the previous fiscal year of the concern.

\*\*\*\*\*